

## REMARKS

Claims 1, and 8-18 are pending in the application. By this amendment, Applicants have cancelled Claim 3, amended Claims 1 and 11, and added Claim 16-18. Currently, Claims 1, 11, and 12 are independent.

The present invention pertains to a method for inducing analgesia without anesthesia for treating non-neuropathic pain. Non-neuropathic pain suitable for treatment according to the invention includes pain associated with sprains; strains; soft-tissue injury (bruises and the like); repetitive motion injury; carpal tunnel syndrome; injury to tendons, ligaments, and/or muscles; conditions such as fibromyalgia, bursitis, castrochondritis, myofascial pain, and pain associated with arthritis, inflammation, contusions, post-surgical pain, and nociceptive pain. According to the method, lidocaine is applied via a transdermal patch applied on or adjacent the locus of the pain.

### Claim rejections under 35 USC § 103

The claims have been rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,411,738 to Hind in view of United States Patent No. 5,741,510 to Rolf et al.. Applicant believes that with the amendments made hereby, this rejection has been obviated. As stated in the rejection, "The Hind patent teaches methods and compositions for reducing pain from shingles by topical administration of lidocaine at a dosage below that which achieves analgesia without inducing anesthesia or systemic side effects." Applicants agree with this characterization. The Action also recognizes that Hind fails to indicate that the compositions disclosed in Hind could be used to treat non-neuropathic pain. To remedy this deficiency of Hind, the Action cites Rolf et al, for the proposition that an analgesic patch can be used to treat arthritis, backache, muscular aches, and strains.

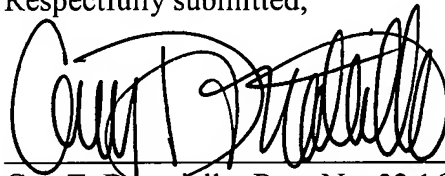
Rolf et al indicates at column 5, lines -33 that "Any of a variety of topical medications can be used in accordance with the present invention. When the patch is used as an **analgesic**, these include trolamine salicylate, methyl salicylate, menthol, camphor, eucalyptus oil, spearmint oil, or a combination thereof. **In other applications**, the medication can include anti-pruritic agents or anti-inflammatory agent such as hydrocortisone, or **anesthetic agents such as benzocaine or lidocaine.**" (emphasis added). Clearly then, Rolf is using lidocaine in it's anesthetic capacity, to relieve pain by anesthetizing the area. The lidocaine patch in Rolf's examples contains 8% lidocaine (see example 8, column 7, line 12). The patch of the present

invention contains only 4-6% lidocaine, and does not cause anesthesia. There is no indication in Rolf that a lower concentration could be used to effectively produce analgesia without anesthesia. It is Rolf's own disclosure that indicates that Rolf uses lidocaine to produce analgesia. One skilled in the art would expect that an anesthesia-causing amount of lidocaine would relieve pain. Lidocaine has been used to this effect for many years. However, there is no indication in Rolf, or elsewhere that lidocaine can be used to effectively produce analgesia without anesthesia.

Regarding the application of Hind to the claims of the present invention, Applicant refers to the argument presented above, that Hind is directed to neuropathic pain and the claims of the present application are limited to the treatment of non-neuropathic pain. Applicant respectfully suggests that Hind is thus inapplicable to the claims of the present application, and respectfully request that this rejection be withdrawn. Applicant notes the unsupported assertion in the action that, "it is the position of the examiner that one of ordinary skill in the art would expect the same result in the treatment of pain, whether it is neuropathic or not." Applicant contends that this is an incorrect assertion. Applicant has submitted scholarly scientific papers refuting this assertion, and respectfully requests that either this evidence be refuted, or this position be abandoned.

Applicants respectfully submit for the reasons set forth above, the claims as amended are patentable over the applied references. Accordingly, early reconsideration and allowance of all pending claims is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Guy T. Donatiello", written over a horizontal line.

Guy T. Donatiello, Reg. No. 33,167  
Attorney for Applicant

GTD:gj

Dated: December 2, 2003  
Endo Pharmaceuticals Inc.  
100 Painters Drive  
Chadds Ford, PA 19317  
(610) 558-9800